DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 5, 2014

Varian Medical Systems, Inc.
% Mr. Peter J. Coronado
Director, Global Regulatory Affairs
3100 Hansen Way
PALO ALTO CA 84304

Re: K140528
Trade/Device Name: TrueBeam, TrueBeam STx, Edge
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 31, 2014
Received: August 4, 2014

Dear Mr. Coronado:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140528

Device Name
TrueBeam and Edge Radiotherapy Delivery System

Indications for Use *(Describe)*
The TrueBeam and Edge Systems are intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation therapy is indicated for adults and pediatric patients.

The TrueBeam and Edge Systems may be used in the delivery of radiation for treatment that includes: brain and spine tumors (such as glioma, meningioma, craniopharyngioma, pituitary tumors, spinal cord tumors, hemangioblastoma, orbital tumors, ocular tumors, optic nerve tumors, and skull based tumors), head and neck tumors (such as unknown primary of the head and neck, oral cavity, hypopharynx, larynx, oropharynx, nasopharynx, sinonasal, salivary gland, and thyroid cancer), thoracic tumors (such as lung cancer, esophageal cancer, thymic tumors, and mesothelioma), gynecologic tumors (such as ovarian, cervical, endometrial, vulvar, and vaginal), gastrointestinal tumors (such as gastric, pancreatic, hepatobiliary, colon, rectal, and anal carcinoma), genitourinary tumors (such as prostate, bladder, testicular, and kidney), breast tumors, sarcomas, lymphoid tumors (such as Hodgkin's and non-Hodgkin's lymphoma), skin cancers (such as squamous cell, basal cell, and melanoma), benign diseases (such as schwannoma, arteriovenous malformation, cavernous malformation, trigeminal neuralgia, chordoma, glomus tumors, and hemangiomas), metastasis (including all parts of the body such as brain, bone, liver, lung, kidney, and skin) and pediatric tumors (such as glioma, ependymoma, pituitary tumors, hemangioblastoma, craniopharyngioma, meningioma, metastasis, medulloblastoma, nasopharyngeal tumors, arteriovenous malformation, cavernous malformation and skull base tumors).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Premarket Notification [510(k)] Summary

TrueBeam/Edge Radiotherapy Delivery Systems

The following information is provided following the format of 21 CFR 807.92(c).

Submitter's Name:	Varian Medical Systems, Inc. 3100 Hansen Way E-110 Palo Alto, CA 94304 Contact Name: Peter J. Coronado Phone: 650.424.6320 Fax: 650.646.9200 Date: 31 July 2014
Proprietary Name:	TrueBeam™/ TrueBeam STx™ Radiotherapy Delivery System Edge™ Radiotherapy Delivery System
Classification Name:	Medical charged-particle radiation therapy system 21 CFR 892.5050, Class II Product Code: IYE
Common/Usual Name:	Medical linear accelerator
Predicate Devices:	TrueBeam Radiotherapy System and Accessories: K123291 CyberKnife Robotic Radiosurgery System and CyberKnife VSI Systems: K102650 Agility™ K123808
Device Description:	The TrueBeam™ and Edge™ Radiotherapy Delivery Systems are medical linear accelerators that integrate the previously cleared Trilogy Radiotherapy system and associated accessories into a single device. The system consists of two major components, a photon, electron, and diagnostic kV X-ray radiation beam-producing component that is installed in a radiation-shielded vault and a control console area located outside the treatment room.
Intended Use Statement	The TrueBeam and Edge Systems are intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation therapy is indicated for adults and pediatric patients.

Indications for Use Statement	The TrueBeam and Edge Systems are intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation therapy is indicated for adults and pediatric patients. The TrueBeam and Edge Systems may be used in the delivery of radiation for treatment that includes: brain and spine tumors (such as glioma, meningioma, craniopharyngioma, pituitary tumors, spinal cord tumors, hemangioblastoma, orbital tumors, ocular tumors, optic nerve tumors, and skull based tumors), head and neck tumors (such as unknown primary of the head and neck, oral cavity, hypopharynx, larynx, oropharynx, nasopharynx, sinonasal, salivary gland, and thyroid cancer), thoracic tumors (such as lung cancer, esophageal cancer, thymic tumors, and mesothelioma), gynecologic tumors (such as ovarian, cervical, endometrial, vulvar, and vaginal), gastrointestinal tumors (such as gastric, pancreatic, hepatobiliary, colon, rectal, and anal carcinoma), genitourinary tumors (such as prostate, bladder, testicular, and kidney), breast tumors, sarcomas, lymphoid tumors (such as Hodgkin's and non-Hodgkin's lymphoma), skin cancers (such as squamous cell, basal cell, and melanoma), benign diseases (such as schwannoma, arteriovenous malformation, cavernous malformation, trigeminal neuralgia, chordoma, glomus tumors, and hemangiomas), metastasis (including all parts of the body such as brain, bone, liver, lung, kidney, and skin) and pediatric tumors (such as glioma, ependymoma, pituitary tumors, hemangioblastoma, craniopharyngioma, meningioma, metastasis, medulloblastoma, nasopharyngeal tumors, arteriovenous malformation, cavernous malformation and skull base tumors).
Technological Characteristics	This device has the same technological characteristics as the previously cleared TrueBeam device K123291. This submission does not introduce any device modifications.
Substantial Equivalence	The indication for use statement for the TrueBeam and Edge radiotherapy delivery systems is similar but not identical to its primary predicate device K123291. The changes made with this submission include specific indications for some typical lesions, tumors and conditions that may be treated with radiation. The addition of this text to the indication statement does not change the therapeutic effect of the device. These treatment sites fall within the previously cleared general indication "to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation therapy is indicated". The device itself is unchanged from the previous submission K123291. The principles of operation, technological characteristics and labeling are substantially equivalent. The functionality and intended use of the TrueBeam and Edge systems is substantially equivalent to that of its predicate devices, CyberKnife and CyberKnife VSI Systems (K102650) and Agility™ K123808, in safety and effectiveness.
Summary of performance testing	No changes have been made to the device and no new testing has been performed.